
University of Arizona Program in Research Integrity Education Monthly Newsletter

A Federally Mandated Compliance Education Program

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One of the nine core instructional areas in the formal instruction in the responsible conduct of research (RCR) is *mentor/trainee responsibilities*. This month's Program in Research Integrity Education (P.R.I.E.) newsletter focuses on mentoring by highlighting an article on Academic Advising entitled "*Reflections from Both Sides of the Desk: From Probationer to Advisor*." This piece is authored by Keith Rocci, M.Ed., Advising Specialist at the University of Arizona.

An excellent University of Arizona site to visit is: <http://advising.arizona.edu/>. You will find it to be a good resource for students, as well as advisors.

The UofA *Advising Handbook* may be found at: <http://advising.arizona.edu/advisors/handbook.htm>. It contains Advising Policies, Academic Policies and Procedures, UA Campus Resources and other valuable information.

Other Advising News: The 2006 Arizona Academic Advising Conference (AZAAC) entitled, "*Extreme Makeover, Advisor Edition: Shaping Student Success*," is being organized and hosted by a planning team of advisors from Pima Community College and the University of Arizona. It is being held in Tucson on May 15 and 16, 2006. For more information regarding this conference, please visit: <http://advising.arizona.edu/azaac.htm>.

Reflections from Both Sides of the Desk: From Probationer to Advisor

By: *Keith Rocci, University of Arizona*

I never imagined that someday I would be advising students in serious academic jeopardy at The University of Arizona. As a UofA student in 1985, I was sporting a GPA well below a 2.0. I lived for my fraternity social events, and worked at various nightclubs. I was also on academic probation. I had no worries about my academic future, mostly because I lacked the maturity to understand the real opportunity I had at the university. Moreover, I lacked the coping skills that I desperately needed to manage my life while attending college. I failed to "get it" and made many poor decisions.

I have changed a great deal since then. After a twelve-year absence, I returned to college in 1997

and completed a B.S. degree. I then completed an M.Ed. in Educational Leadership, followed by an M.Ed. in Educational Technology. On May 13, 2006, I will complete an M.A. in Information Resources and Library Science. It took many years, but I learned the value of higher education, which helped me to become a lifelong learner.

Today, twenty one years after my first college experience ended, I sit in my office with students who live the kind of life I did back then. They come into my office saying all the right things and displaying what appears to be sincere concern, but, in the end, some really don't get it. Luckily, the best part of my job is that some do get it and eventually turn things around and graduate.

Several aspects of higher education have changed in those two decades since I was a college student. The obvious change is with technology. This new and very eager generation is connected, wireless, and looking for new ways to make the process easier. Other student changes include their racial and ethnic diversity, gender, enrollment status, age, residence, disability status, and sexual orientation (Gordon & Habley, 2000). These changes are important characteristics that advisors need to understand.

Even with these changes, students in danger of academic jeopardy still have some basic needs that can significantly impact their academic success. As an academic advisor, I need to understand that my actions are important to promoting student change. I also need to develop strategies to address the needs of today's very complex students. In the next five paragraphs, I will explain the needs that I believe these students have and explain the value of addressing these needs.

First, students need to feel important in the academic advising process. Their feelings as they embark toward academic failure need to be considered in order to change the trajectory toward success. It could be argued that far too often we as a society focus on the negative. A strength-based approach that involves building on what is already working can be an effective tool when advising students who are in academic jeopardy. It is important to investigate the successes they have had and expand upon them.

Second, students need to know that somebody cares. An effective academic advisor establishes a relationship with each student with one controlling expectation in mind: graduation. This familiar saying may sound simplistic but rings true: students rarely care how much you know until they know how much you care.

Third, students need to be rewarded for their efforts. Appropriate praise can be a powerful tool and can create more successes. These validations can help even the most struggling student to work harder to turn things around.

Fourth, students need to be contacted regularly. Communication can be a powerful asset to even the most experienced advisor. Call the student. E-mail the student. When you see the student on campus, say hi and ask how he or she is doing. At some institutions, there are literally thousands of students roaming the campus during the day. If you see your advisees, make their day and say hi to them.

Fifth, students need to be in a non-threatening relationship. A great way to ease a student's concerns is to find a common ground to create dialogue. I generally try to make a connection with a student based on something in his or her background. This gesture requires some research and also a desire to learn about new things. For example, I may make reference to a hometown sports team as we are making small talk on the walk to my office. This conversation is a nice transition into the content of the appointment. I might also refer to the student's plans for spring or fall break, holiday travel plans, or something else that is interesting to him or her. Students generally want to become connected to their college and to people there. Individualize the process, and you can create a powerful trust. When this connection occurs, many students tend to grasp the importance of succeeding in higher education.

As this reflection concludes, the value of the advisor must be reinforced. An advisor who seriously cares about student outcomes, enjoys interaction with students, and sincerely believes that each student can succeed will ultimately gain satisfaction from his or her experiences.

References

Gordon, V. N., & Habley, W. R. (Eds). (2000). *Academic advising: A comprehensive handbook*. San Francisco: Jossey-Bass.

About the Author

Keith Rocci is an advising specialist at the University of Arizona. He can be reached at rocci@email.arizona.edu or (520) 626-8718.

"Good advising may be the single most underestimated characteristic of a successful college experience."

Light, R.J. (2001) Making the most of college. Cambridge, MA: Harvard University Press

BUILDING RESPECT

A successful mentoring relationship is founded on mutual respect between mentor and student. Here are some guidelines on promoting respect:

- ✚ **Take student seriously.** A question or problem that seems trivial or irrelevant to you might not be, or it might mask a more serious issue. Listen carefully.
- ✚ **Don't dictate answers.** Suggest various "road maps," but allow students to choose the destination.
- ✚ **Be frank and direct.** Let students know what you can (and can't) offer in the mentoring relationship.
- ✚ **Help students develop self-esteem.** Provide praise as well as suggestions for improvement.
- ✚ **Invite other mentors.** Acknowledge that no single person can fill all a student's needs.
- ✚ **Address fears without belittling.** Know about a student's money worries, low self-esteem, fear of failure, parental pressures, and doubts about belonging. Don't wait for fears to grow into problems that might cause a student to stumble or even leave your program.
- ✚ **Meet on "neutral ground."** Don't always meet in your office; a student might be more comfortable at a laboratory bench, local cafeteria, or jogging track.

Source: *Advisor, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering*. National Academy Press, Washington, D.C., 1997.

<http://www.nap.edu/readingroom/books/mentor/>

UNIVERSITY OF ARIZONA RESEARCH SUPPORT SERVICES GROUP (RSSG)

Institutional Biosafety Committee



The Institutional Biosafety Committee is pleased to inform the research community that it now has training on the proper uses of biological safety cabinets on their website. Simply log on to www.ibc.arizona.edu, and click the training link.

This site is a useful reference for those who already have experience using biosafety cabinets, and can serve as an initial training step for new laboratory personnel.

HUMAN SUBJECTS PROTECTION PROGRAM

≡Highlights≡

Data Safety Monitoring Plan*

Research personnel may be unfamiliar with the concept of a Data Safety Monitoring Plan and the need for a Data Safety Monitoring Committee or Board. Consideration of such a plan is part of the federal regulations ... in that “when appropriate, the research **plan** makes adequate provisions for monitoring the data collected to ensure the safety of subjects.” [21CFR 56.111 & 45 CFR 46.111]

What is a Data Safety Monitoring Plan?

A Data Safety Monitoring Plan (DSMP) provides a formal process of monitoring the data collected to ensure the safety of subjects. A DSMP should assign the responsibility for data and safety monitoring to the Principal Investigator, Sponsor/Committee, or a Data Safety Monitoring Board (DSMB). If the responsibility for data monitoring is the Sponsor/Committee or Board, the plan should explain the number of individuals responsible for this task and their qualifications for functioning in this capacity.

Additionally, a DSMP should include frequency of data analysis. For example, will the data be analyzed by time (every 6 months), by participant (after every 10 participants), or by event (after a fatality)? The plan should include stopping rules regarding the potential outcomes of the study that could have an impact on the safety or welfare of the study participants. Finally, the DSMP should describe how findings on data safety monitoring activities will be communicated to outside entities (e.g., Institutional Review Boards)

When do I need a Data Safety Monitoring Committee or Board?

For many studies, a group of experts would be necessary in order to provide meaningful evaluation of study data. These individuals may either be comprised as a Committee (Sponsor designated employees or employees of an institution) or a Board (group of experts in the field independent of the study Sponsor). These groups evaluate the study for integrity of the data as well as the risk/benefit profile for current and future participants. Data Safety Monitoring Boards are usually reserved for studies in which there are major risks to research

participants. Greater than minimal risk research can be monitored and evaluated by a Committee and high risk research monitored by a Board.

In conclusion, the research study should make adequate provisions for data and safety monitoring sufficient to protect the rights and welfare of research participants. The research study should describe the basic parameters of the data safety monitoring process. Currently, the application for the Human Subjects Protection Program includes a section that asks for information pertaining to data safety monitoring. The response to questions in that section should be adequate in order to fully describe the protection of research participants.

*Amdur, R. (2006). Provisions for Data Monitoring. In E. A. Bankert and R. J. Amdur (Eds.), Institutional Review Board Management and Function (pp. 160-165). Sudbury, MA: Jones and Bartlett.



Radiation Control

Laser Systems and Laser Products

The Arizona Radiation Regulatory Agency (ARRA) regulates the possession and use of Class 3b and Class 4 lasers and requires the University of Arizona (UA) to maintain a Laser Safety Program and register these two classes of lasers. An important aspect of the University’s Laser Safety Program is an accurate laser inventory. The UA Radiation Control Office (RCO) maintains the Laser Safety Program and the laser inventory for the University.

A laser system consists of a laser head and its power supply and is usually easily identifiable as a laser. Its classification label is usually readily visible. A laser product is equipment that utilizes one or more lasers as part of a larger system for a specific application. A CD player is a good example of a laser product (although, as a consumer product, it is exempt from ARRA regulation).

A laser product can be labeled in such a way that does not readily indicate that it contains a regulated laser. Principal investigators may also be unaware that the laser system or product they are using is required to be registered with the ARRA. It is imperative that a newly acquired Class 3b or 4 laser system or a laser product containing a Class 3b or 4 laser be registered with the ARRA and a hazard evaluation be performed by the RCO prior to use.

Regulated laser products or applications that may utilize a regulated laser, but not contain the word “laser” in their names include:

Products

Aberrometers
 Confocal microscopes
 Doppler velocimeters
 Ellipsometers
 Fiber optics tests systems
 Flow cytometers
 Interferometers
 Light shows
 Optical tweezers
 Raman spectrometers
 Mass spectrometers

Applications

Range Finders
 Material milling
 Microdissection
 Engraving
 Holography
 Motion Capture

If you identify a laser system or product, contact the RCO to determine whether it requires registration.

****Please note that most consumer products, such as laser pointers, lasers printers, and CD and DVD players and recorders are not regulated by the ARRA and do not need to be reported to the RCO.**

Responsibility for the possession and safe use of the laser system or product is generally a faculty member, but may be other appointed personnel under certain circumstances. If a laser cannot be assigned to a faculty member, it will be considered the responsibility of the department head.

Please contact Keith Carsten (626-5469/carsten@radcon.arizona.edu), or Carolyn Vieira (626-5468/vieira@radcon.arizona.edu) if you have questions about laser safety and regulatory requirements, or if you need assistance with determining the status of a laser system or product.

University of Arizona – Animal Care Quality Care for Research Animals



Animal Hazards Program/Occupational Health Provisions

The following is a memorandum which was distributed via email on April 17, 2006, to the *Animal Research Community* by Dr. Leslie P. Tolbert, Vice President for Research, Graduate Studies and Economic Development.

The University of Arizona is committed to providing employees and students with a work and learning environment that minimizes exposure to unsafe conditions. One important component of meeting this commitment is the Occupational Health portion of the Animal Hazards Program, in which each individual in contact with an animal, animal tissues, fluids or wastes, either under

laboratory or field conditions, is assessed for hazardous risks. This program is funded by the University of Arizona and is provided free of charge to qualifying individuals.

Federal and other regulations require an occupational health program for personnel working with laboratory and other animals. A description of the University's Occupational Health Program is included in the Assurance of Compliance required by the National Institutes of Health. And to further assure compliance with all applicable occupational health and safety standards, the international Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) conducts triennial inspections of our institution.

The Animal Hazards Health and Safety Instruction document developed by our Occupational Health and Safety Committee and revised by our Animal Hazards Program Committee, serves as the University of Arizona's written policy for occupational risk reduction for those using or exposed to animals in research or teaching. The document is available for review at:

<http://www.iacuc.arizona.edu/animalhazardsprogram.shtml>.

If you have questions concerning the Occupational Health portion of the Animal Hazards Program, please contact Carol Dugger, Animal Hazards Program Coordinator, at 621-2568, or at dugger@health.arizona.edu. You will find additional information on the program at the following: http://www.health.arizona.edu/webfiles/health_services_animal_hazards.htm.

By cooperating and complying with the requirements of this program, you are assisting the University in maintaining its accreditation status, funding for animal research, and reputation as a center for excellence in research and teaching. Thank you.



News from HIPAA.....

April 6, 2006

OCR Releases Updated Unofficial Version of Full HIPAA Text

The Office for Civil Rights (OCR) has posted the updated Unofficial Version of the HIPAA Administrative Simplification Regulation Text, as amended through February 16, 2006. This document includes the final "HIPAA Administrative Simplification Enforcement Rule" that was published at 71 Federal Register 8389 (February 16, 2006), as well as for the first time the HIPAA Administrative Simplification rules at 45 CFR Part

162 that are administered by the Centers for Medicare & Medicaid Services (CMS). Thus, this version now includes all of the final HIPAA Administrative Simplification regulations.

[Read the "Updated Unofficial Version of HIPAA Administrative Simplification Regulation Text \(PDF\)"](#)

Good Laboratory Practices (GLP)

The Federal Food, Drug, and Cosmetic Act and Public Health Service Act require that sponsors of FDA-regulated products submit evidence of their product's safety in research and/or marketing applications. These products include food and color additives, animal drugs, human drugs and biological products, human medical devices, diagnostic products, and electronic products. FDA uses the data to answer questions regarding:

- The toxicity profile of the test article.
- The observed no adverse effect dose level in the test system.
- The risks associated with clinical studies involving humans or animals.
- The potential teratogenic, carcinogenic, or other adverse effects of the test article.
- The level of use that can be approved.

The following resources are provided to help investigators, sponsors, and contract research organizations who conduct nonclinical studies on investigational new drugs to comply with U.S. law and regulations covering good laboratory practice (GLP).

- [Bioresearch Monitoring: Good Laboratory Practice](#)
- [Regulatory Pharmacology and Toxicology](#)
- [Toxicological Principles for the Safety of Food Ingredients \(Redbook 2000\)](#)

Code of Federal Regulations: [Good Laboratory Practice for Nonclinical Laboratory Studies \(21 CFR Part 58\)](#)

Upcoming Conferences/Workshops

Teaching Research Ethics –
A Workshop at Indiana University

Thirteenth Annual Workshop, May 10-13, 2006

The thirteenth annual Teaching Research Ethics Workshop will be held at Indiana University from May 10-13, 2006. Session topics include an over-

view of ethical theory, trainee and authorship issues, conflicts of interest, using human subjects in clinical and non-clinical research, and responsible data management. Information and registration are available at <http://poynter.indiana.edu>.

May 15-16, 2006

Extreme Makeover, Advisor Edition: *Shaping Student Success*

Tucson, AZ

Co-sponsor: Pima Community College and The University of Arizona

July 24-25, 2006

[Mentoring and Supervision for the Responsible Conduct of Research](#)

St. Louis, MO

Co-sponsor: Washington University School of Medicine

September 14-15, 2006

Statistics, Images, and Perceptions of Truth: Detecting Research Bias and Misconduct

Birmingham, AL

Co-sponsor: University of Alabama School of Medicine

October 16-17, 2006

Fourth Annual RCR Expo

Quebec City, Canada

Contact: LNguyen-Khoa@osophs.dhhs.gov

December 1-3, 2006

[Research Conference on Research Integrity](#)

Tampa, FL

Co-sponsors: Association of American Medical Colleges, American Association for the Advancement of Science

Abstracts due: April 28, 2006 (see ORI web site for details on submitting abstracts and to obtain a conference schedule: <http://ORI.hhs.gov>).

Questions should be addressed to Nick Steneck at nsteneck@umich.edu.

University of Arizona Program in Research Integrity Education staff:

Alice C. Langen, Director, Research Compliance
Ruth K. Daniels, Program Coordinator and Editor of the P.R.I.E. Newsletter rhk@u.arizona.edu
P.R.I.E. – Program phone number: (520) 626-6282
The P.R.I.E. newsletter is researched and compiled by Ruth Kurash Daniels.

Words of Wisdom:

"That best academy, a mother's knee."

~ James Russell Lowell